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**APPLICATION NUMBER: 60/561,389**

**FILING DATE: April 12, 2004**

**RELATED PCT APPLICATION NUMBER: PCT/US05/12122**



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# PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

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60/561389  
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TITLE OF THE INVENTION (280 characters max)					
PLANAR MULTI-SITE INJECTION SYSTEM					
Direct all correspondence to: CORRESPONDENCE ADDRESS					
<input checked="" type="checkbox"/> Customer Number		26822		 Place Customer Number Bar Code here PATENT TRADEMARK OFFICE	
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ENCLOSED APPLICATION PARTS (check all that apply)					
<input checked="" type="checkbox"/>	Specification	Number of Pages	7	<input type="checkbox"/>	CD(s), Number
<input checked="" type="checkbox"/>	Drawing(s)	Number of Sheets	3	<input checked="" type="checkbox"/>	Other (specify)
<input type="checkbox"/>	Application Data Sheet. See 37 CFR 1.76				
					ASSIGNMENT; COVER SHEET
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Respectfully submitted,

SIGNATURE

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04/12/2004

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27,792

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P19LARGE/REV05

PLANAR MULTI-SITE INJECTION SYSTEM

The present invention is generally directed to the administration of a medicament and is more particularly  
5 directed to a multi-site injection system for dermal delivery of a medicament.

SUMMARY OF THE INVENTION

10 A multi-site injection system in accordance with the present invention generally includes a guide plate having a plurality of openings therethrough and needle plate having a plurality of needles projecting therethrough with each needle being aligned with a corresponding opening and a guide plate.

15

The needle plate is movable from a first position with the needles position behind a top surface of the guide plate to a second position with the needles projecting from the top plate through the openings. A plunger base is provided for  
20 moving the needle plate from the first to the second position.

In one embodiment of the present invention, the needles are coated with a medicament and in another embodiment of the present invention the needles include lumens in communication  
25 with a medicament reservoir disposed in the plunger base for delivery of the medicament into a stratum corneum of a users skin.

The needles and openings may be arranged in order to applicate the medicament to a users skin in a define pattern which, may be a symmetrical radial pattern, an asymmetrical radial pattern or a concentric pattern which may or may not be circular. A rectilinear pattern of needles may be utilized in accordance with the present invention and the medicament preferably comprises botulinum toxin.

#### BRIEF DESCRIPTION OF THE DRAWINGS

10

The advantages and features of the present invention will be better understood by the following description when considered in conjunction with the accompanying drawings in which:

15

Figure 1 is a perspective view of a multi-site injection system in accordance with the present invention generally showing a guide plate having a plurality of openings therethrough, a plunger base and a plurality of needles projecting from the guide plate;

20

Figure 2 is a partial cross section of one embodiment of the present invention showing a reservoir of medicament disposed in the plunger base with needle lumens in fluid communication therewith and disposed with needle points generally flush with a top surface of the guide plate;

25

Figure 3 is a cross sectional view similar to that shown in Figure 2 illustrating movement of the plunger base for

protruding the needles from the top surface of the guide plate and into a stratum corneum of a users skin;

Figure 4 illustrates continued pressure on the plunger base for forcing medicament through the needle lumens and into the stratum corneum of the users skin; and

Figures 5 and 6 illustrate various needle patterns which may be suitable for various applications and areas of treatment on a users skin.

#### DETAILED DESCRIPTION

With reference to Figure 1, there is shown an injection system 10 generally including a guide plate 12 having a plurality of openings therethrough along with a needle plate 20 including a plurality of needles 24 shown extending through the openings 16 and projecting from a top surface 28 of the guide plate 12. Also shown is a plunger base 30 for moving the needle plate from a first position with the needles 24 positioned generally behind the top surface 28, see Figure 2 to a second position with the needles 24 projecting from the top surface 28 as shown in Figures 1, 3 and 4.

The needles 24 may be coated with a medicament, such as, for example, botulinum toxin.

The guide plate 12, needle plate 20, needles 24 and base 30 may be made from any suitable material and the needles

3152

preferably are about 28 gauge and 1mm in length. Use of the multi-site injection system 10 for delivery of a medicament into the stratum corneum of a users skin is illustrated in Figures 2-4.

5

As shown, the needle plate is configured in any suitable manner for being moveable from a first position shown in Figure 2 with the needles positioned behind, or flush with the top surface 28 of the needle plate 28 to a second position shown in Figures 3 and 4 with the needles 24 projecting from the top surface 28 through the openings 16..

The plunger base 30 preferably includes and defines a reservoir 42 between the needle plate and the base 30 for containing the medicament 34.

20

Incompressibility of the medicament 34 enables movement of the plunger base 30 to move the needle plate 20 from the first to the second position as indicated by the arrows 46.

Continued movement of the plunger base 30 forces medicament 34 through needle lumens 50 and collapse of the reservoir 42. The guide plate 12, needle plate 20, and plunger based 30 may be integrally formed with a diaphragm arrangement, not shown, for enabling the relative motion hereinabove described. Other suitable configurations should be considered to be within the scope of the present invention.

It should be appreciated that while the system 10 shown in Figure 1 illustrates, holds, or openings 16 and needles arranged in a generally symmetrical radial pattern, other patterns may be utilized for delivery of a medicament to body areas requiring different patterns of application. Figures 5 and 6 illustrate systems 54, 56 showing an asymmetrical radial pattern and a rectilinear pattern respectively.

Although there has been hereinabove described a specific planer multi-site injection system in accordance with the present invention for the purpose of illustrating the manner in which the invention may be used to advantage, it should be appreciated that the invention is not limited thereto. That is, the present invention may suitably comprise, consist of, or consist essentially of the recited elements. Further, the invention illustratively disclosed herein suitably may be practiced in the absence of any element which is not specifically disclosed herein. Accordingly, any and all modifications, variations or equivalent arrangements which may occur to those skilled in the art, should be considered to be within the scope of the present invention as defined in the appended claims.



## WHAT IS CLAIMED IS:

1. A multi-site injection system comprising:
  - a guide plate having a plurality of openings  
5 therethrough;
  - a needle plate having a plurality of needles projecting therefrom, each needle being aligned with a corresponding opening in said guide plate, said needle plate being movable from a first position with the needles  
10 positioned behind a top surface of said guide plate to a second position with the needles projecting from the top surface through the openings; and
  - a plunger base for moving said needle plate from the first to the second position.  
15
2. The system according to claim 1 wherein said needles are coated with a medicament.
3. The system according to claim 1 wherein said plunger  
20 bore includes a reservoir for medicament and needles include lumen therethrough in communication with said reservoir for delivery of the medicament into a stratum corneum of a users skin.
- 25 4. The system according to any one of claims 1-3 wherein the needles and opening are arranged in a symmetric radial pattern.

5. The system according to any one of claims 1-3 wherein the needles and opening are arranged in an asymmetric radial pattern.

5 6. The system according to any one of claims 1-3 wherein the needles and openings are arranged in a concentric pattern.

7. The system according to claim 6 wherein said  
10 concentric pattern is circular.

8. The system according to any one of claim 1-3 wherein the needles and opening are arranged in a rectilinear pattern.

15 9. The system according to any one of claims 1-3 said medicament comprises botulinum toxin.

10. A multi-site injection system comprising:  
a needle plate having a plurality of needles  
20 projecting therefrom; and  
botulinum toxin disposed with the needles for delivery to a stratum corneum of a user.

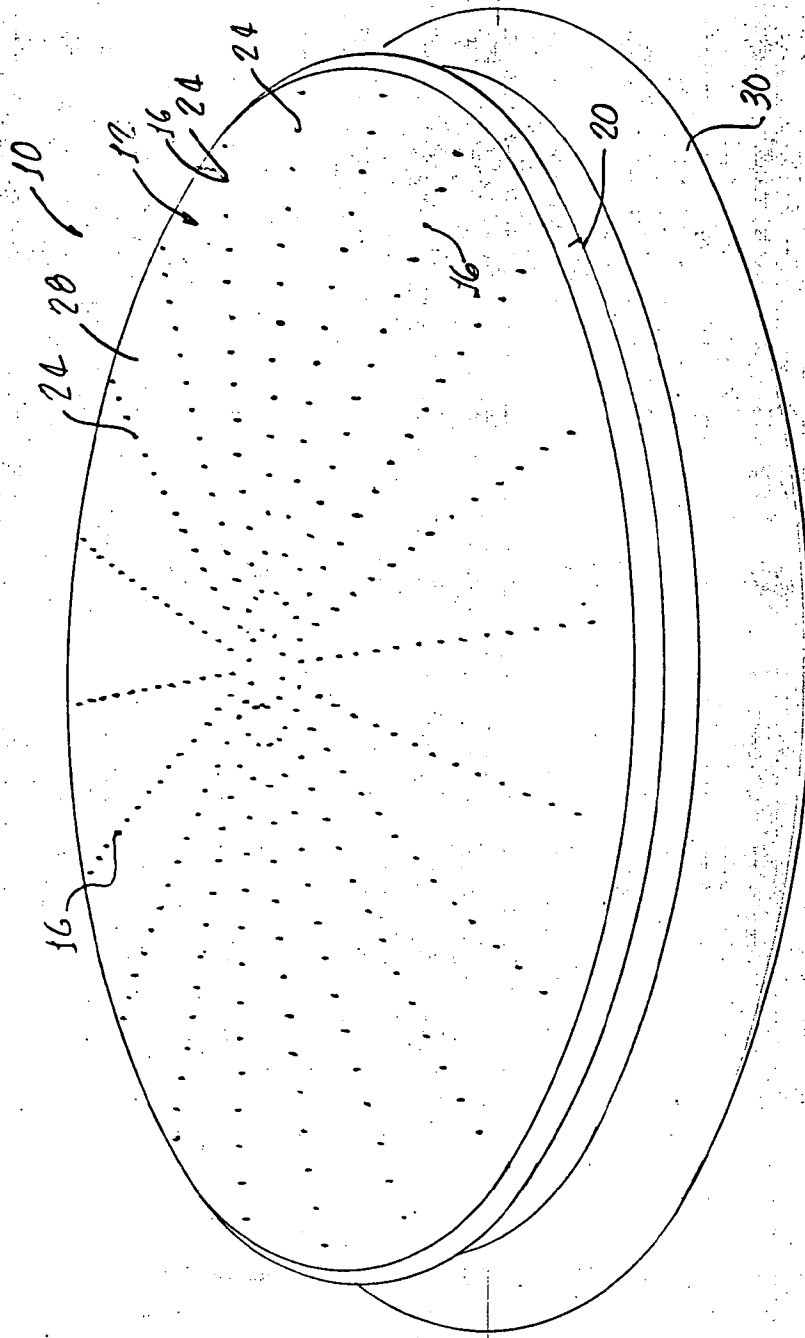


FIG. 1.

FIG. 2

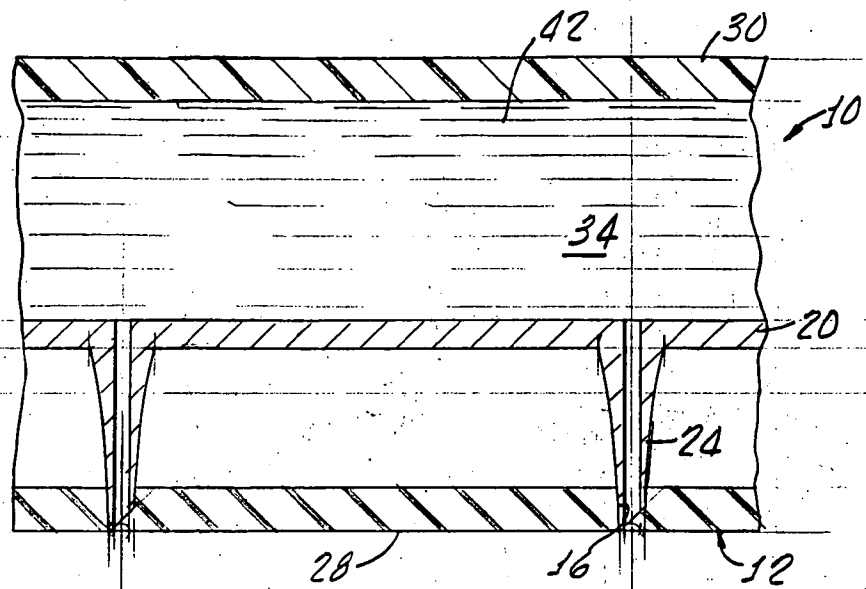


FIG. 3

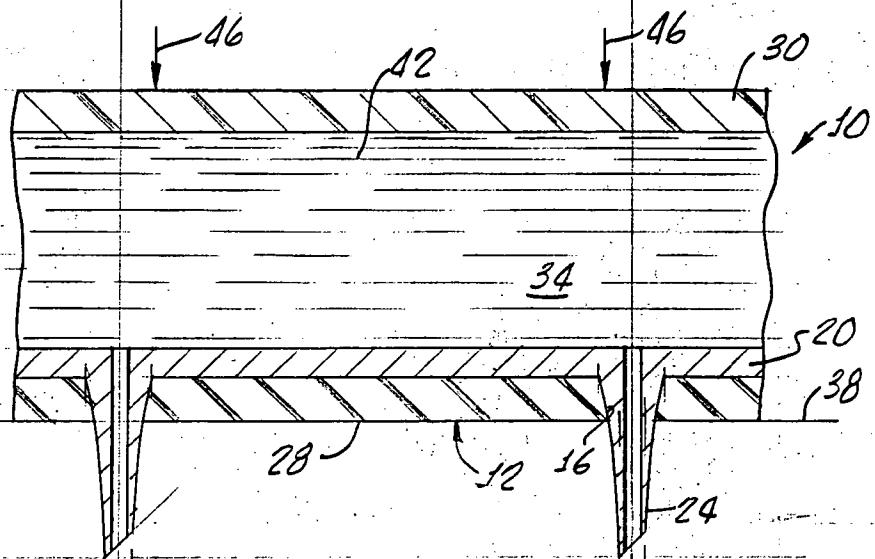
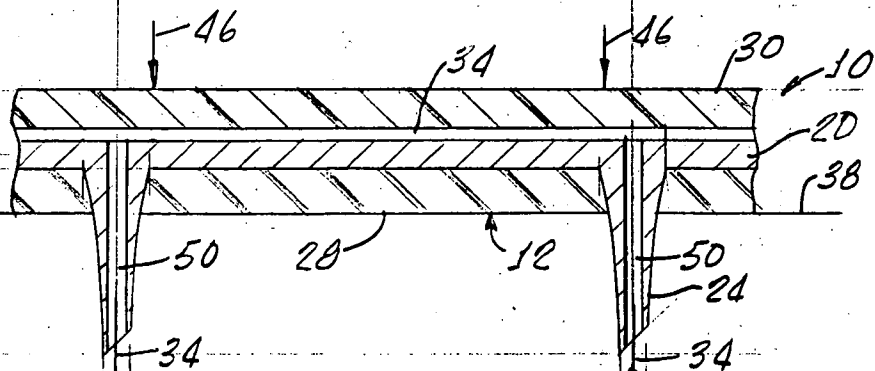
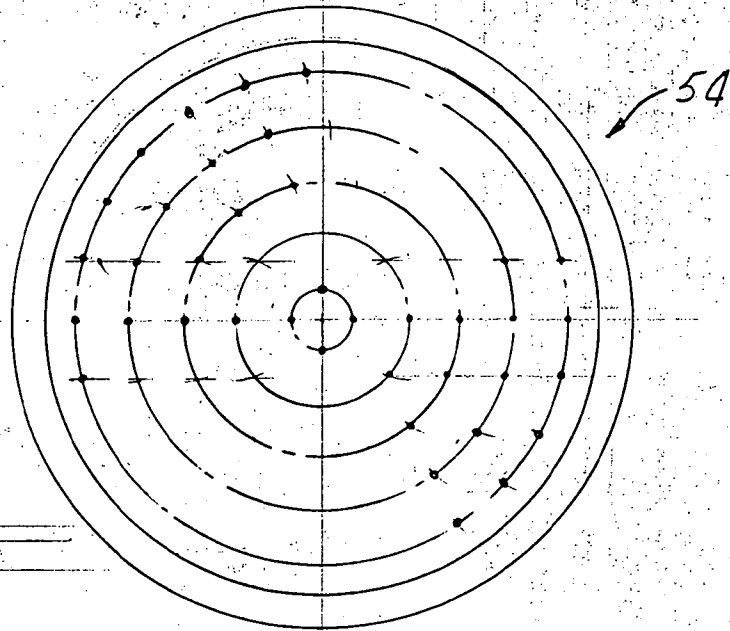
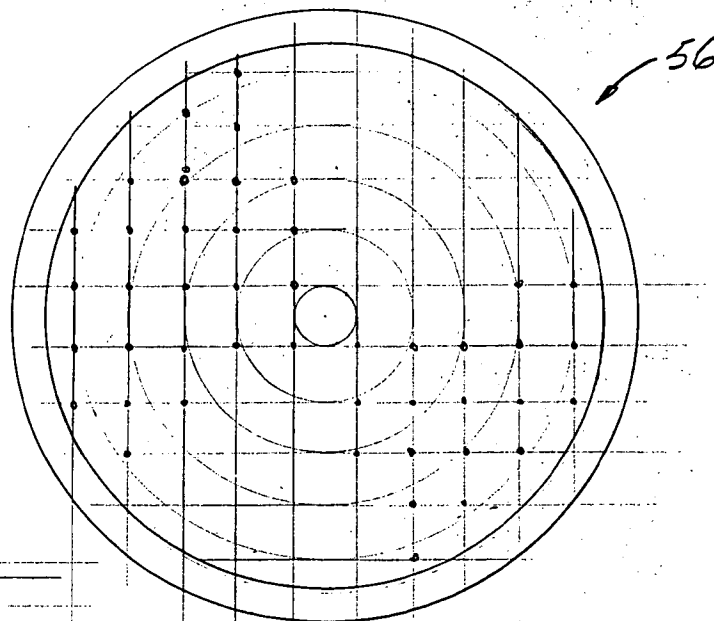


FIG. 4



FIG. 5.FIG. 6.